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Diane Dunn McKay

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Zenhausern, F.	
Serial No. 09/332,659	Group Art Unit: 1655
Filed: June 14, 1999	Examiner: Chakrabarti, A.
For: APPARATUS AND METHOD FOR MONITORING MOLECULAR SPECIES WITHIN A MEDIUM	

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Washington, D.C. 20231

SIR:

AMENDMENT

In response to the Office Action dated September 17, 2001, please amend the application as follows:

In the Claims:

Please amend claims 1, 14 and 34 as follows:

Sub B1

1. (Amended) A method for monitoring information in a medium, the medium comprising at least one biomolecule, the method comprising the steps of:

screening the medium with a screening means comprising a n number of sensing probes, where n is an integer of at least one so that more than one physical, chemical, or physico-chemical change of a gas or vapor phase of at least one secondary product of the

biomolecule, a biomolecule byproduct or the biomolecule which defines the information is detected by the probe to produce at least one signal output;

transferring the signal output to a signal processing means responsive to differences in electromagnetic properties of the signal for generating a final output;

receiving the final output into a pattern recognition means sufficient to generate a measurement pattern of the information;

sorting the information in accordance with a set of class boundaries of physical, chemical or physico-chemical changes of the biomolecule representative of the presence and quantitative amounts of the biomolecule in the medium; and

monitoring the sorted information.

14. (Amended) The method according to claim 1, wherein at least part of the information detected by the probe is changes in the at least one secondary product of the biomolecule.

34. (Amended) A method of claim 1 wherein the biomolecule is at least one of DNA, RNA, AIDS, a nucleotide, or cancer.

Please add claims 37-41 as follows:

37. (New) The method of claim 1 wherein said screening step further comprises reacting one or more volatile organic tags with the medium to attach to said biomolecule.

38. (New) The method of claim 1 wherein the medium is a mixture of polymerase chain reaction (PCR) products, PCR byproducts or reagents.

39. (New) The method of claim 1 wherein said monitoring step monitors an amplification reaction.

40. (New) The method of claim 1 further comprising the step of:

controlling a polymerase chain reaction after the step of monitoring the sorted information.

A4

41. (New) The method of claim 40 wherein said screening step further comprises reacting one or more volatile organic tags with the medium to attach to said biomolecule.

Please cancel claims 20, 22-24 and 27-33.

REMARKS

The Office Action dated September 17, 2001 has been carefully considered. Claims 1, 14 and 34 have been amended. Claims 37-41 have been added. Claims 20, 22-24 and 27-33 have been cancelled. Claims 1-19, 21, 25, 26 and 34-41 are in this application.

The Examiner objected to the dependency of original claim 34 on nonelected claim 33. Claim 34 has been amended to depend from elected claim 1.

Original claim 1 was rejected under 35 U.S.C. § 112 as indefinite. Claim 1 has been amended to obviate the Examiner's objection. Claim 1 has also been amended to further define the present invention. Support for this amendment is found throughout the specification and in particular, on page 17, lines 12-16. No new matter has been entered.

The claims were rejected under 35 USC § 112 as indefinite. Applicant has amended the claims for clarity. Each of the claims has been amended for clarity to encompass the full scope and breadth of the invention. Applicants believe that the claims would have been allowable as originally filed. Accordingly, Applicants assert that no claims have been narrowed within the meaning of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., No. 95-1066, 2000 WL 1753646 (Fed. Cir. Nov. 29, 2000).

New claims 37-41 have been added to define additional features of the present invention. Claim 37 is disclosed throughout the specification and in particular on page 26, line 22 – page 27, line 5 of the specification. Claim 38 is disclosed throughout the specification and in particular on page 26, lines 1-5. Claim 39 is disclosed throughout the specification and in particular on page 27, lines 6-14. Claims 40 and 41 are disclosed

throughout the specification and in particular on page 27, lines 6-25 and page 35, line 12 – page 36.

The previously-presented claims were rejected under 35 U.S.C. § 102 as anticipated by U.S. Patent No. 6,100,026 to Nova et al. Applicant submits that the teaching of this reference does not disclose or suggest the invention defined by the present claims.

Nova et al. teach tagging molecules during synthesis of chemical compounds using matrices with memories. Each molecule is linked to the support matrix with a memory imprinted on the surface of the matrix. The memory is programmed to identify the linked molecule. A second molecule is linked to the first linked molecule. The synthesized compound is identified by the optically-readable symbol corresponding to the support matrix to which the compound is linked. The support matrix can be a luminescent moiety.

In contrast to the invention defined by the present claims, Nova et al. do not teach or suggest a method for monitoring information of a medium containing at least one biomolecule in which the medium is screened with a sensing probe so that more than one physical, chemical or physico-chemical change of a gas or vapor phase of the secondary product of the biomolecule, the by product of the biomolecule or the biomolecule is detected. To the contrary, Nova et al. detect a species based on fluorescence properties of linked compounds. However, Nova et al. do not teach or suggest sensing a species based on its gas or vapor phase. Accordingly, the invention defined by the present claims is not anticipated by Nova et al.

The previously-presented claims were rejected under 35 U.S.C. § 103 as obvious in view of Nova et al. in combination with Payne et al., Ashe et al. or Ghahramani et al.

Payne et al. disclose a method for detecting a microorganism by extracting gas or vapor associated with the microorganism and flowing the same over an array of sensors. The microorganism is a bacteria typically occurring during a fermentation process. However, Payne et al. do not teach or suggest a method for monitoring a medium comprising at least one biomolecule. Instead, Payne et al. teach monitoring a microorganism which is not related to the same family of biological species as the

biomolecule of the present invention. In addition, Payne et al. do not teach or suggest that the method monitors a medium of polymerase chain reaction products and reagents or the step of controlling a polymerase chain reaction based on the monitored information, as defined by respective new claims 37 and 38.

Furthermore, there is no motivation to one skilled in the art to combine Nova et al. directed to use of a solid matrix material with a memory for biochemical synthesis with Payne et al. directed to microorganisms. Rather, there is no suggestion in the Payne et al. reference that a different family of biological species could be detected. Accordingly, the invention defined by the present claims is not obvious in view of Nova et al. alone or in combination with Payne et al.

Ashe et al. disclose a method for controlling the manufacture of lubricating oils involving the steps of distillation, extracting, and dewaxing for controlling operating units having feedstocks boiling above 350°C. In contrast to the invention defined by the present claims, Ashe et al. do not teach or suggest monitoring a medium including at least one biomolecule. Rather, Ashe et al. is directed to an unrelated oil refining method. Further, Ashe et al. do not teach or suggest sensing gas or vapor information of a secondary product of the biomolecule, a biomolecule by product or a biomolecule.

In addition, there is no motivation to one of ordinary skill in the art to combine Nova et al. directed to use of a solid matrix material with a memory for biochemical synthesis with Ashe et al. directed to a method for preparing lubricating oils. Further, even if the references were combined, the combination does not teach the invention defined by the present invention since neither Nova et al. alone or in combination with Ashe et al. teach or suggest sensing a species based on its gas or vapor phase.

Ghahramani et al. disclose a multiple hazard marker system to be combined with a deployment vehicle. The deployment vehicle can be a military tank. The sensed hazards are microorganisms, bacteria and virus. However, Ghahramani et al. do not teach or suggest a method for monitoring a medium comprising at least one biomolecule. To the contrary, Ghahramani et al. teach monitoring a microorganism which is not related to the same family of biological species as the biomolecule of the present invention. Furthermore, there is no motivation to one skilled in the art to combine Nova et al.

directed to us of a solid matrix material with a memory for biochemical synthesis with Ghahramani et al. directed to microorganisms.

Furthermore, none of the cited prior art teach any method to monitor a biomolecule using the techniques described in the present invention. In the present invention, any biomolecule can be partitioned in at least a gas phase such as during a thermal assisted enzymatic reaction, which gas phase can be detected using the method of the present invention. In addition, the invention defined by the present claims describes an unique method to detect the amplification event in real-time of an enzymatic reaction, and in particular for the polymerase chain reaction (PCR), exploiting the intrinsic gas phase of said biomolecule when it is undergoing such a physico-chemical reaction. A second mechanism to interrogate a biomolecule within the scope of the present invention is to detect a change in the medium surrounding the biomolecule, the change mediated by either a by-product of a reaction of the biomolecule within the medium, or the change mediated by the consumption of at least a reagent or the like in the medium in the presence of said biomolecule or its amplification products or by-products. The amplification products or by-products or both or the like are preferably detectable in a gas phase. Another approach claimed in the present invention is the use of a volatile tag attached to said biomolecule that can act as a label similar to a fluorophore. The use of more than one volatile tags can be used to further identify the biomolecule.

Accordingly, the invention defined by the present claims is not obvious in view of Nova et al. in combination with Payne et al., Ashe et al. or Ghahramani et al.

In view of the foregoing, Applicant submits that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this

application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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DATE: February 18, 2002

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